IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Timothy BATEMAN et al.

Serial No.

Filed: concurrently herewith

For: PATIENT VENTILATION

DEVICES

Art Unit:

Examiner:

Atty Docket: 0100/0134



#2

SUBMISSION OF PRIORITY DOCUMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Attached hereto please find a certified copy of applicant's patent application No. 0023250.4 filed in Great Britain on September 21, 2000. Applicant requests the benefit of said September 21, 2000 filing date for priority purposes pursuant to the provisions of 35 USC 119.

Respectfully submitted,

Louis Woo, Reg. No. 31,730

Law Offices of Louis Woo

1901 N. Fort Myer Drive, Suite 501

Arlington, Virginia 22209

Phone: (703) 522-8872

Date:

Aug 29 2001







The Patent Office Concept House Cardiff Road Newport South Wales NP10 8QQ



I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed

Dated

1 August 2001

Patents Form 1/77

e 16)





Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

THE PATENT OFFICE H 2 1 SEP 2000

RULE 97

NEWPORT

22SEP00 E570312-1 C26047 P01/7700 0.00-0023250.4The Patent Office

> Cardiff Road Newport South Wales NP10 8QQ

1. Your reference

2. Patent application number (The Patent Office will fill in this part)

21 SEP 2000

0023250.4

3. Full name, address and postcode of the or of each applicant (underline all surnames)

SMITHS INDUSTRIES PUBLIC LIMITED COMPANY 765 FINCHLEY ROAD LONDON

NW11 8DS

Patents ADP number (if you know it)

728708002

00495705009

If the applicant is a corporate body, give the country/state of its incorporation

GB

4. Title of the invention

PATIENT VENTILATION DEVICES

5. Name of your agent (if you have one)

J. M. FLINT

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

765 FINCHLEY ROAD LONDON NW11 8DS

Patents ADP number (if you know it)

1063288002

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number (if you know it)

Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing (day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

YES

- a) any applicant named in part 3 is not an inventor, or
- there is an inventor who is not named as an applicant, or
- c) any named applicant is a corporate body.See note (d))

Patents Form 1/77

 Enter the number of sheets for any of the following items you are filing with this form.
 Do not count copies of the same document

Continuation sheets of this form

Description

5

Claim(s)



Abstract
Drawing(s)

2 + -

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

Lin

Date 20/09/00

12. Name and daytime telephone number of person to contact in the United Kingdom

J.M. FLINT

020 8457 8220

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.
- b) Write your answers in capital letters using black ink or you may type them.
- c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.
- e) Once you have filled in the form you must remember to sign and date it.
- f) For details of the fee and ways to pay please contact the Patent Office.

PATIENT VENTILATION DEVICES

This invention relates to patient ventilation devices.

The invention is more particularly concerned with face masks for use in ventilating patients.

Conventional face masks have a cone-shape mount with a soft cuff extending around its edge, which is applied against the skin of the patient around the nose and mouth. A port opens into the interior of the mount so that air or other gas can be supplied to the patient's nose and mouth. Usually, these face masks are held against the face manually or by means of a strap extending around the patient's head. The pressure needed to ensure an effective seal can cause damage to the patient's skin. It can also be difficult to achieve an effective seal without applying manual pressure and this is a disadvantage because it occupies a nurse or clinician. Alternatively, it has been proposed in US3357426 and WO99/25410 that a face mask be secured to the patient's face by means of an adhesive.

It is an object of the present invention to provide an alternative ventilation device.

According to one aspect of the present invention there is provided a ventilation device including a first member adapted to extend across the patient's mouth, adhesive means adapted to seal the first member around the mouth and nose, a tube member extending through the first member and having a first end located externally and a second end extending into the patient's mouth such that the patient can be ventilated via the tube member.

The tube member is preferably removable from the first member.

According to another aspect of the present invention there is provided a ventilation device including an outer sac of a flexible material, the sac having a closed end and an open end adapted to be applied to the face of the patient around the mouth and nose, the device including a filling within the sac of a conformable material adapted to mould to the contours of the face, a tubular member extending through the conformable material by which the patient can be ventilated, and the device being adhesive around at least its periphery such as to retain the device on the face.

According to a further aspect of the present invention there is provided a ventilation device including a member adapted to extend across the mouth and nose of a patient, an opening through the member in the region of the mouth, and the member having an adhesive surface adapted to seal around the mouth and nose of the patient such that the nose is blocked and the mouth opens through the opening enabling ventilation via the mouth.

The device preferably includes a tube insertable through the opening such that one end of the tube extends into the patient's mouth and the other end protrudes externally.

A ventilation device according to the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of the rear of the device before use;

Figure 2 is a side elevation view of the device of Figure 1 in use;

Figure 3 is a perspective view of the rear of a modification of the device shown in Figures 1 and 2; and

Figure 4 is a perspective view of the rear of an alternative device.

With reference first to Figures 1 and 2, the device takes the form an adhesive face mask arranged to block the nose and enable ventilation through the mouth. The device comprises a flexible sheet or plate 1 the rear surface 10 of which is adhesive, such as in the form of a hydrocolloid or other skin-compatible adhesive. The plate 1 has two cheek pads 11 and 12 extending laterally on opposite sides, a small, semi-circular, downwardly-projecting chin pad 13 and a larger upwardly-projecting nose pad 14. The nose pad 14 has four split lines 15 to enable it to be shaped about the nose. The device also has an opening through the plate 1 in the form of a short, rigid plastics fitting 16 secured to the plate and projecting through it at a location centrally across its width, so that it is in line with the mouth. The fitting 16 enables a vent tube 17 to be inserted, the vent tube having one end 18 that extends into and opens within the mouth and an opposite end 19 that projects externally forwardly from the device. In use, the forward end 19 of the tube is either left open, when the patient is breathing spontaneously, or is connected to ventilation or anaesthesia equipment, when necessary. The vent tube 17 can be removed from the fitting 16 when not required, such as when initially securing the device to the patient's face. Alternatively, the device could have a vent tube permanently fixed with the plate 1. The device is fitted by aligning the fitting 16

with the patient's mouth and smoothing the pads 11 to 14 onto the skin. The vent tube 17 can then be inserted.

With reference now to Figure 3, there is shown a modified form of the device in which the plate 1' has a central region 20' that is non-adhesive, clear and transparent so that the region around the mouth can be viewed by the clinician. This region 20' may be a flexible film or a rigid clear plastics. Figure 3 shows a vent tube 17' permanently fixed with the plate 1' and having a patient end 18' that terminates flush with the patient-side surface of the plate, so that it does not extend within the mouth.

With reference now to Figure 4 there is shown an alternative form of ventilation device. This comprises an outer sac 40 of a flexible material such as rubber or silicone rubber, which has a substantially triangular section and tapers in width from its closed forward end 41 to its open rear or patient end 42. The size and shape of the rear end 42 of the sac 40 are such that it can fit around the nose and mouth of the patient. The sac 40 is filled with two different materials. It contains an outer layer 43 of an adhesive, such as a hydrocolloid, and an inner mass 44 of a conformable material, such as a gel. The hydrocolloid layer 43 is relatively thick, typically around 10mm, so that the rear face of the device presents an adhesive peripheral region that is sufficiently wide to ensure secure retention on the skin. The adhesive layer need not extend around the entire inner surface of the sac 40 providing that it forms an adhesive peripheral region around the open end 42 of the sac. Instead of the adhesive being inside the sac, it could, for example, be provided on an externally-projecting flange. The device is completed by a vent tube 46 extending along the sac 40 through the gel 44. The rear end 47 of the tube 46 projects a short distance from the

open end 42 of the sac 40 so that it extends into the patient's mouth. The forward end 48 of the tube 46 projects externally from the forward end of the device to enable connection to ventilation equipment.

The gel 44 and adhesive 43 are protected by a release sheet, which is removed just before use. The device is then held up to the patient's face and the rear end 47 of the vent tube 46 is located in the patient's mouth. The device is pressed firmly against the face so that the gel 44 moulds about the contours of the nose and mouth and so that the adhesive 43 bonds with the skin. Once firmly in position, the device can be released since it is self-supporting.

The arrangements of the present invention enable reliable ventilation via the mouth without the need for continuous manual pressure and without the need for straps or the like, which can cause skin damage after prolonged use. The device of the invention can be used on patients of differing builds without the need to provide a wide range of different sizes.

[Y:\PATENTS\SPEC\00\AFM.doc]





